IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Sharon L. Morris, R.N., and Dean E. Morris

DATE: October 4, 1996

SERIAL NO.: 08/286,413 GROUP ART UNIT: 2111

FILED: August 5, 1994 EXAMINER: R. Gibson

FOR: "Automatic Surgical Sponge Counter and Blood Loss Determination System"

ATTORNEY DOCKET NO.: A94087US (51929/1)

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DECLARATION OF DEAN E. MORRIS UNDER 37 C.F.R. § 1.132

Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Sir:

I, the undersigned, hereby declare that I am familiar with the above-referenced invention as claimed in the claims presented in the Rule 116 Response dated September 24, 1996 filed in the above-referenced patent application.

It would not have been obvious to use RF tags capable of being encoded with information about the sponges attached to the sponges at the time the invention was made because RF tags capable of being encoded with information about the sponges were prohibitively expensive at that time (attached is a price list revised shortly after the patent application was filed - the prices were even higher when we first conceived the invention). My wife and I realized that, if the price of the RF tags capable of being encoded with information about the sponges came down enough, they could be used as disclosed in the present application.

The undersigned hereby declares that all statements made of his own knowledge are true and that all statements made on information and belief are believed to be true, and that this statement is made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,

10-10-96
Date

Dean E. Morris

51929A01.DEC/sn

SCHEDULE C: AUTHORIZED PRODUCTS AND PRICES

The following are undiscounted list prices. VAR discount is calculated according to Schedule A. Contact Director, Industrial Products for larger quantities. Prices subject to change without notice.

Tag prices are for Standard Industrial Format (S10-CRC5) random-unique coding. All passive probe-programmed tags are subject to a non-discountable surcharge of $1.25. per tag. There is no surcharge on active tags.

Tags LIST Price

		26 - 250	251 - 2500	2,501 - 5,000	5,001 - 10,000	10,001 - 20,000	20,001 - 50,000
IT-21E	Card Tag	5.25	5.13	4.91	4.41	4.00	3.76
IT-34E	Rugged Tag	12.00	12.00	11.00	10.00	9.00	8.00
IT-36E	HighTemp Rugged Tag	35.00	34.40	31.00	28.50	27.10	26.00
IT-39E	Lipstick Tag	8.00	7.70	7.40	7.00	6.60	6.00
IT-47E	Rugged VID Tag w/Leads	22.50	19.60	17.65	16.20	15.45	15.45
IT-52E	MiniDisc Tag	3.50	3.50	3.50	3.25	3.00	3.00
IT-54E	HiStress Disc Tag	3.33	3.33	3.33	3.00	2.69	2.69
IT-61E	BigDisc Tag	5.85	5.45	5.05	4.70	4.45	4.25
IB-11E	Active Card Tag	39.60	34.50	31.05	28.50	27.20	26.10
IB-44E	ActiveRugged VID Tag	39.60	34.50	31.05	28.50	27.20	26.10

Readers LIST Price

		1 - 10	11 - 25	26 - 100	101 - 500
IR-2E	Focused Point Reader	1135	1060	990	920
IR-12E	Compact Reader	500	480	460	430
IR-24E	Long Range Reader 8 x 36	1400	1220	1060	920
IR-36E	Long Range Reader 16 x 36	1600	1390	1210	1050
IR-50E	General Purpose Reader	1095	1020	950	880
IR-52E	HiStress Vehicle-Mount Reader 9 x 9	2600	2500	2400	2305
IR-60E	Underground VID Reader	2125	2000	1950	1875
IR-68E	Hockey Puck Reader	1035	960	890	830
IR-100E	Portable Reader	1195	1150	1080	1030
IR-200E	Dual Technology Portable Reader	2395	2350	2250	2200

COURT CASE

MONITORING BLOOD LOSS—WHO'S RESPONSIBLE?

Controversy centers on the OR nurses.

WHEN THIRTEEN-YEAR-OLD LAURA UHR underwent surgery at Lutheran General Hospital in Park Ridge, Ill., she experienced copious blood loss, went into cardiac arrest, and died. Her parents sued the hospital.

At trial, Dr. Harry Cohen, an expert witness for the plaintiffs, testified that the anesthesiologist failed to properly monitor Laura's blood loss, which Dr. Cohen estimated to be from 30% to 40% of her total blood volume. Yet she received no transfusions until after her heart had stopped.

According to other trial testimony, blood loss is typically monitored by weighing saturated surgical sponges used to absorb blood, then subtracting the dry weight. The resulting blood weight, along with a running total of blood loss, is written on tape and placed where the anesthesiologist can easily see it.

The anesthesiologist, Dr. Ronnett, testified that he didn't remember the nurses weighing the sponges or telling him what they estimated the blood loss to be. He also said, however, that he didn't pay attention to what the nurses were doing because monitoring blood loss was his responsibility. He kept track by looking at the sponges as they were used and keeping a mental tally.

Further questioning centered on a nurse's chart notation indicating that the patient had lost 1,100 ml of blood at one point during surgery. Dr. Ronnett said that if a nurse had told him this, he would have paid attention and might have reevaluated his blood-loss estimate.

Mary Gilmore, a nurse who testified as an expert witness, explained the standard of care expected of OR nurses. She stated that the failure to weigh sponges and communicate the results was a deviation from this standard.

After deliberation, the jury awarded Laura's parents $1,870,000. The hospital appealed.

The appellate court affirmed the verdict, holding that the testimony supported the conclusion that the OR nurses had failed to weigh the sponges and communicate their findings to Dr. Ronnett. The court found the hospital liable, even though the anesthesiologist was an independent contractor, not a hospital employee. ■

Source: Uhr v. Lutheran General Hospital, 589 N.E. 2d 723 (Ill.App. 1 Dist. 1992).

Oral cyclosporine-vecuronium interaction

To the Editor:

Prolongation of the neuromuscular blocking effect of vecuronium with intravenous preparations of cyclosporine has been described.[1,2] We observed this interaction in a 36-yr-old man two months after renal transplant receiving oral cyclosporine when he returned for internal urethrotomy. He was taking oral cyclosporine 180 mg bid, and azathioprine 75 mg and prednisolone 30 mg od. Physical examination and preoperative investigations were normal. On the morning of the operation, he took one dose of each of the three immunosuppressives. Premedication was with pentazocine 20 mg and phenergan 20 mg *im* and anaesthesia was induced with thiopentone 5 $mg \cdot kg^{-1}$ followed by vecuronium 0.08 $mg \cdot kg^{-1}$ *iv*, $O_2 + N_2O$ (40:60) and halothane 0.5%. Neuromuscular function was assessed continuously. Haemodynamic stability was maintained throughout the one-hour operation. No additional vecuronium was given. Neuromuscular blockade was reversed with neostigmine 0.05 $mg \cdot kg^{-1}$ and atropine 0.02 $mg \cdot kg^{-1}$ *iv* after two definite and a faint third response to train-of-four stimulation were observed. Though the patient was awake and cooperative, incoordinate body movements, inability to sustain head lift, inadequate respiratory efforts and poorly sustained 50 Hz tetanus suggested residual neuromuscular blockade. The patient's temperature, serum electrolytes and arterial blood gas analysis were normal. Further neostigmine 1.0 mg and atropine 0.5 mg after ten minutes had no effect. Positive-pressure ventilation was continued for about three hours after which a satisfactory return of the neuromuscular function enabled extubation. In the absence of obvious renal, hepatic or metabolic derangement in this patient, the prolonged neuromuscular blocking effect of vecuronium was probably due to drug interaction. While azathioprine[3] and chronic steroid therapy[4] antagonize non-depolarizing neuromuscular blockade, cyclosporine appears to prolong it.[1,2,5] Intravenous preparations of cyclosporine, however, contain cremophor as solvent, which may potentiate vecuronium-induced blockade[5] and thus be partly responsible for this interaction. Oral cyclosporine (Sandimmum, Sandoz) does not contain cremophor. Thus, in light of the above interaction, continuous monitoring of neuromuscular block in post-transplant patients is reemphasized.

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Anaesthetists overestimate blood loss

To the Editor:

We wish to report the results of a study to determine the accuracy of anaesthetists' visual estimate of blood volume on surgical sponges. Known premeasured volumes of blood (diluted to a haematocrit of 30%) ranging from 5 to 125 ml were added to seven dry and three wet gauze sponges. Thirty-one randomly selected anaesthetists (mean years anaesthesia experience = 8) overestimated blood volumes on sponges by 86% (±7) (SEM). For the three different-sized sponges studied, overestimation was more pronounced with the smaller sponge (Raytex 4″ × 4″) than with the adult laparotomy tape (18″ × 18″, 4 ply) ($P < 0.025$) or the paediatric laparotomy tape (4″ × 18″, 4 ply) ($P < 0.03$). Also, overestimation (%) errors were larger when smaller quantities of blood were added to adult and paediatric laparotomy tapes ($P < 0.01$). Increasing number of years of anaesthesia experience did not correlate ($r = 0.16$) with more accurate estimation.

Previously published studies showed that both surgeons and anaesthetists tended to underestimate total intraoperative blood loss.[1,2] We attempted to reproduce, in a controlled manner, the most practical method of blood loss assessment: visual estimation. The study confirmed that visual estimation of blood loss on sponges is inadequate. The amount of blood on surgical sponges can account for up to one-half the blood lost during an operation.[3] Our findings may be especially relevant in pae-

diatric anaesthesia where smaller volumes of blood are absorbed by small sponges. In adult anaesthetic practice, the overestimation of blood on surgical sponges may not be clinically important as accuracy is increased on larger sponges with larger volumes of blood. If accurate measurements of this component of intraoperative blood loss are important, weighing sponges in addition to observing haemodynamic and haematocrit changes is necessary.

We were interested in a simple, inexpensive clinical aid to correct visual overestimation. Medical Action Industries, Inc. (Farmindale, NY), the manufacturer of surgical gauze sponges at our institution, reports an absorptive capacity per square inch of 0.23 ± 0.01 ml of normal saline for the 4-ply, 22 × 24 thread gauze sponge we studied. That implies a maximum absorptive volume of 75 ± 2 ml for the adult laparotomy tape and 16.7 ± 0.5 ml for the paediatric laparotomy tape. Educating operating room physicians about the maximum absorptive volume of surgical gauze sponges may reduce overestimation.

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